

# General

### Guideline Title

Tools for assessing outcomes in studies of chronic cough: CHEST guideline and Expert Panel report.

### Bibliographic Source(s)

Boulet LP, Coeytaux RR, McCrory DC, French CT, Chang AB, Birring SS, Smith J, Diekemper RL, Rubin B, Irwin RS, CHEST Expert Cough Panel. Tools for assessing outcomes in studies of chronic cough: CHEST guideline and Expert Panel report. Chest. 2015 Mar;147(3):804-14. [111 references] PubMed

### **Guideline Status**

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

### Recommendations

# Major Recommendations

The grades of recommendation (1A–2C, consensus-based [CB]) and the approach to rating the quality of evidence are defined at the end of the "Major Recommendations" field.

- In adult and adolescent patients (≥14 years of age) complaining of chronic cough, the Expert Panel recommends that validated and reliable health-related quality of life (QoL) questionnaires be used as the measurement of choice to assess the impact of cough on patients (Grade 1B).
- 2. In adults and adolescents with chronic cough, the Expert Panel recommends the Cough-Specific Quality-of-Life Questionnaire and Leicester Cough Questionnaire, as they are the most extensively studied and commonly used previously validated and reliable cough-specific health-related QoL questionnaires to assess the impact of cough (Grade 1B).
- 3. In children (<14 years of age) with chronic cough, the Expert Panel recommends that validated and reliable health-related QoL questionnaires be used as the measurement of choice to assess the impact of cough (Grade 1B).
- 4. In children (<14 years of age) with chronic cough, the Expert Panel recommends the Parent Cough-Specific Quality of Life Questionnaire, the most extensively studied and commonly used previously validated and reliable health-related QoL questionnaire, as the measurement of choice to assess the impact of cough (Grade 1B).
- 5. To standardize the development, utilization, and reporting of cough-specific QoL questionnaires, the Expert Panel suggests that cough counting alone not be used to establish validity of the questionnaires (CB).
- 6. To standardize the development, use, and reporting of cough severity by visual analog scales (VASs) or numeric rating scales, the Expert Panel suggests that they be used in standard fashion (CB).
- 7. To ensure the integrity of health-related QoL questionnaires and other patient-reported outcomes that have been shown to be valid and

- reliable, the Expert Panel suggests that a modified version should not be used and reported unless the modified version has been shown to be reliable and valid (CB).
- 8. In adult and adolescent patients with cough of any duration, the Expert Panel suggests that tussigenic challenges have a role in research settings to understand mechanisms of cough (CB).
- 9. In patients of all ages, the Expert Panel recommends acoustic cough counting to assess cough frequency but not cough severity (Grade 1B).

### **Definitions**

American College of Chest Physicians (CHEST) Grading System

Grade of Recommendation	Balance of Benefit vs. Risk and Burdens (Strength of the Recommendation: Level 1 or 2)	Methodologic Strength of Supporting Evidence (Quality of Body of Evidence: A, B, C, or CB)	Implications
Graded evidence-b	ased guideline recommen	dations	
Strong recommendation, high-quality evidence (1A)	Benefits clearly outweigh risk and burdens or vice versa	Consistent evidence from randomized controlled trials (RCTs) without important limitations or exceptionally strong evidence from observational studies	Recommendation can apply to most patients in most circumstances. Further research is very unlikely to change confidence in the estimate of effect.
Strong recommendation, moderate-quality evidence (1B)	Benefits clearly outweigh risk and burdens or vice versa	Evidence from RCTs with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence from observational studies	Recommendation can apply to most patients in most circumstances. Higher-quality research may well have an important impact on confidence in the estimate of effect and may change the estimate.
Strong recommendation, low- or very-low-quality evidence (1C)	Benefits clearly outweigh risk and burdens or vice versa	Evidence for at least one critical outcome from observational studies, case series, or from RCTs with serious flaws or indirect evidence	Recommendation can apply to most patients in many circumstances. Higher-quality research is likely to have an important impact on confidence in the estimate of effect and may well change the estimate.
Weak recommendation, high-quality evidence (2A)	Benefits closely balanced with risks and burden	Consistent evidence from RCTs without important limitations or exceptionally strong evidence from observational studies	The best action may differ depending on circumstances or patient's or societal values. Further research is very unlikely to change confidence in the estimate of effect.
Weak recommendation, moderate-quality evidence (2B)	Benefits closely balanced with risks and burden	Evidence from RCTs with important limitations (inconsistent results, methodologic flaws, indirect or imprecise) or very strong evidence from observational studies	Best action may differ depending on circumstances or patient's or societal values. Higher-quality research may well have an important impact on confidence in the estimate of effect and may change the estimate.
Weak recommendation, low- or very-low- quality evidence (2C)	Uncertainty in the estimates of benefits, risks, and burden; benefits, risk, and burden may be closely balanced	Evidence for at least one critical outcome from observational studies, case series, or RCTs, with serious flaws or indirect evidence	Other alternatives may be equally reasonable. Higher-quality research is likely to have an important impact on confidence in the estimate of effect and may well change the estimate.
Nongraded consen	sus-based suggestions		
Consensus-based (CB)	Uncertainty due to lack of evidence but expert opinion that benefits outweigh risk and burdens or vice versa	Insufficient evidence for a graded recommendation	Future research may well have an important impact on confidence in the estimate of effect and may change the estimate.

# Clinical Algorithm(s)

# Scope

# Disease/Condition(s) Chronic cough **Guideline Category** Evaluation Management Screening Clinical Specialty Allergy and Immunology Family Practice Internal Medicine **Pediatrics** Pulmonary Medicine **Intended Users** Advanced Practice Nurses Nurses Physician Assistants Physicians Respiratory Care Practitioners Guideline Objective(s) To assess the performance of tools designed to measure cough frequency, severity, and impact in adults, adolescents, and children with chronic cough and make recommendations or suggestions related to these findings

# Target Population

Adults, adolescents, and children (<14 years of age) complaining of chronic cough

### Interventions and Practices Considered

- 1. Validated and reliable health-related quality of life (QoL) questionnaires
  - Cough-Specific Quality-of-Life Questionnaire
  - Leicester Cough Questionnaire
  - Parent Cough-Specific Quality of Life Questionnaire

- 2. Development, use, and reporting of cough severity by visual analog scales (VASs) or numeric rating scales
- 3. Avoiding use of the modified versions of questionnaires
- 4. Consideration of tussigenic challenges to understand mechanisms of cough
- 5. Cough counting to assess cough frequency

# Major Outcomes Considered

- Diagnostic accuracy (e.g., sensitivity, specificity, positive predictive value, negative predictive value, validity, reliability, responsiveness, feasibility)
- Therapeutic efficacy (e.g., change in clinical practice, impact on patient or provider decision-making)
- Patient outcome efficacy (e.g., acceptability, quality of life (QoL), chest pain, depression, anxiety)

# Methodology

### Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

# Description of Methods Used to Collect/Select the Evidence

The subcommittee on assessment of cough based its recommendations on a recently published comparative effectiveness review (CER) commissioned by the Agency for Healthcare Research and Quality (AHRQ) and a corresponding summary.

#### Methods

Investigators searched MEDLINE, EMBASE, and the Cochrane Database of Systematic Reviews through June 2012 to identify English-language evaluative studies of instruments used to assess the frequency or impact of acute or chronic cough. Included studies had to (1) compare one cough assessment tool to another or to clinical assessment of cough or (2) evaluate change in response to treatment over time with a given tool.

The literature search began with the inception of these databases; the last literature search date for the CER was June 4, 2012. The literature search was subsequently updated by two authors of the CER, who are also members of the subcommittee on assessment of cough, using the same selection criteria used for the original CER project. This updated literature search identified 27 eligible studies published between June 2012 and November 2013, inclusive, that were not included in the CER.

The CER included an analytic framework constructed by using the general approach of specifying the population of interest, interventions, comparators, outcomes, timing of outcomes, and settings (PICOTS) to address the following key question: In adults and adolescents (≥14 years of age) and children (<14 years of age), what is the comparative diagnostic accuracy, therapeutic efficacy, and patient outcome efficacy of instruments used to assess cough? The criteria used to screen articles for inclusion and exclusion at both the title-and-abstract and the full-text screening stages are detailed in Table 1 in the original guideline document. Figure 1 in the original guideline document depicts this key question within the context of the PICOTS framework. The figure shows that the CER compared the diagnostic accuracy, therapeutic efficacy, and patient outcome efficacy of instruments to assess the severity, frequency, and impact of cough on patient outcomes. Subgroups considered included children aged, <14 years and patients with differing underlying cough etiologies. The subcommittee formulated the additional key clinical research questions presented in the "Major Recommendations" section.

### Number of Source Documents

The original comparative effectiveness review (CER) identified 115 articles representing 121 unique studies that underwent full-text review and 78 studies that met inclusion criteria for the review. The updated literature search identified an additional 105 studies for full-text review, 27 of which met inclusion criteria, for a total of 105 eligible studies.

Methods Used to Assess the Quality and Strength of the Evidence

# Rating Scheme for the Strength of the Evidence

The strength of the evidence for the key question was rated using the general approach described in the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews* and the *Methods Guide for Medical Test Reviews* (see the "Availability of Companion Documents" field). In brief, the approach required assessment of four domains: risk of bias, consistency, directness, and precision. These domains were considered qualitatively, and a summary rating of high, moderate, or low strength of evidence was assigned after discussion by two reviewers (see Table 2 in the original guideline document).

### Methods Used to Analyze the Evidence

Meta-Analysis

Systematic Review with Evidence Tables

### Description of the Methods Used to Analyze the Evidence

The strength of the evidence for the key question was rated using the general approach described in the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews* and the *Methods Guide for Medical Test Reviews* (see the "Availability of Companion Documents" field). In brief, the approach required assessment of four domains: risk of bias, consistency, directness, and precision. These domains were considered qualitatively, and a summary rating of high, moderate, or low strength of evidence was assigned after discussion by two reviewers (see Table 2 in the original guideline document). In some cases, high, moderate, or low ratings were impossible or imprudent to make. For example, when no evidence was available or when evidence on the outcome was too weak, sparse, or inconsistent to permit any conclusion to be drawn, a grade of insufficient was assigned. Two members of the subcommittee on assessment of cough revised the strength of evidence conclusions reported in the comparative effectiveness review (CER) to include additional information reported in the studies identified by the updated literature search. Prior to publication, experts reviewed this guideline and addressed all suggestions and criticisms.

See the systematic review (see the "Availability of Companion Documents" field) for information on data abstraction and synthesis for the original review. See also the methodology document (see the "Availability of Companion Documents" field) for additional information about the quality assessment for the updated literature search.

### Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

# Description of Methods Used to Formulate the Recommendations

The methodology used by the American College of Chest Physicians (CHEST) Guidelines Oversight Committee to select the Expert Cough Panel chair and the international panel of experts and to perform the synthesis of the evidence to develop the recommendations and suggestions has been previously published in the methodology and CHEST guideline development documents (see the "Availability of Companion Documents" field). In addition to the quality of the evidence, the recommendation grading also includes a strength of recommendation dimension (see the "Rating Scheme for the Strength of the Recommendations" field). In the context of practice recommendations, a strong recommendation applies to almost all patients, whereas a weak recommendation is conditional and only applies to some patients. In the context of research recommendations, such as the ones in this guideline, the Expert Panel intended for a strong recommendation (grade 1) to imply that the Expert Panel recommend using a particular cough assessment in almost all the cases and instances where such a tool is being considered. The strength of recommendation here is based on consideration of three factors: balance of benefits to harms, patient values and preferences, and resource considerations. Harms incorporate risks and burdens to the patient, which, for example, can include convenience or inconvenience, difficulty of administration, and invasiveness. These in turn affect patient preferences. The resource considerations go beyond economics and should factor in time and other indirect costs. The authors of these recommendations have considered these parameters in determining the strength of the recommendations and associated grades.

Key questions and parameters of eligibility were developed for this topic. Existing guidelines, systematic reviews, and primary studies were assessed for relevance and quality and were used to support the evidence-based graded recommendations or suggestions. A highly structured consensus-based (CB) Delphi approach was used to provide expert advice on all guidance statements. The total number of eligible voters for each guidance statement varied based on the number of managed individuals recused from voting on any particular statements because of their potential conflicts of interest (COIs). For example, four panel members were recused from developing and voting on the recommendations that included mentioning specific quality of life (QoL) instruments. Writing committee member COIs related to the recommendations were identified and are presented in a COI grid (see the online supplement [see the "Availability of Companion Documents" field]). Transparency of process was documented. Further details of the methods have been published in the methodology and CHEST guideline development documents.

The Executive Committee of the CHEST Expert Cough Panel convened a subcommittee to formulate recommendations or suggestions that pertain to the assessment of cough frequency and severity. This subcommittee on assessment of cough based its recommendations on a recently published comparative effectiveness review (CER) commissioned by the Agency for Healthcare Research and Quality (AHRQ) and a corresponding summary (see the "Availability of Companion Documents" field). Various members of the Expert Cough Panel provided the stimulus for the AHRQ CER and were invited to participate as key informants, technical expert panelists, and peer reviewers.

### Rating Scheme for the Strength of the Recommendations

American College of Chest Physicians (CHEST) Grading System

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# Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

### Method of Guideline Validation

External Peer Review

Internal Peer Review

# Description of Method of Guideline Validation

#### Review Process

After the Cough Executive Committee provided final approval, the NetWorks, Guidelines Oversight Committee (GOC), and Board of Regents disseminated manuscripts and supporting documentation for review. The American College of Chest Physicians (CHEST) NetWorks of interested members, in the areas of Airways Disorders, Allied Health, Clinical Pulmonary Medicine, Pediatric Chest Medicine, Pulmonary Physiology Function and Rehabilitation, and Respiratory Care, reviewed the content of the manuscripts. Members from the CHEST Board of Regents and GOC reviewed both content and methods, including consistency, accuracy, and completeness.

The CHEST Journal peer review process overlapped with the later rounds of these reviews. All ideas for modification were marked as mandatory or suggested, responded to or justified, and tracked through the multiple rounds of review. The CHEST Presidential line of succession provided the final approval allowing submission to the journal.

# **Evidence Supporting the Recommendations**

# Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

# Benefits/Harms of Implementing the Guideline Recommendations

#### Potential Benefits

More-precise assessments could help to determine the actual impact of cough on patients and allow for valid evaluation of outcomes, providing reliable measurement of the effect of antitussive therapies

### Potential Harms

Not stated

# **Qualifying Statements**

### **Qualifying Statements**

American College of Chest Physicians (CHEST) guidelines are intended for general information only, are not medical advice, and do not replace professional medical care and physician advice, which always should be sought for any medical condition. The complete disclaimer for this guideline can be accessed at <a href="http://www.chestnet.org/Guidelines-and-Resources/Guidelines-and-Consensus-Statements/CHEST-Guidelines">http://www.chestnet.org/Guidelines-and-Resources/Guidelines-and-Consensus-Statements/CHEST-Guidelines</a>

# Implementation of the Guideline

# Description of Implementation Strategy

#### **Dissemination**

After publication, the guidelines were promoted to a wide audience of physicians, other health-care providers, and the public through multiple avenues. Press releases were prepared for both the lay and medical media, with major outreach efforts to all relevant print, broadcast, and Internet media. Panelists located in various large media markets were identified as potential spokespersons for interviews. Social media promotion was facilitated over Twitter, Facebook, American College of Chest Physicians (CHEST) e-Communities, internal and external blogs, and other communication routes. Blast communications were sent to CHEST members with links to the publication and postings on CHEST's Web site.

In addition to publication in *CHEST*, other derivative products were prepared to help with implementation, including slide sets, algorithms, and other clinical tools. These derivative products are posted on the CHEST Web site and will be made available in CHEST Guidelines. CHEST Guidelines will be the repository for the most current recommendations and suggestions from all CHEST guidelines, consensus statements, and hybrid documents. This online repository will also house a collection of related resources.

Associations that appointed representatives earlier in the process were asked to consider endorsing the approved guidelines for listing in the final publication. These organizations were requested to help promote the publication to their memberships through newsletters, Web sites, and other means.

# Implementation Tools

Mobile Device Resources

Resources

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

#### **IOM Domain**

Effectiveness

Patient-centeredness

# Identifying Information and Availability

# Bibliographic Source(s)

Boulet LP, Coeytaux RR, McCrory DC, French CT, Chang AB, Birring SS, Smith J, Diekemper RL, Rubin B, Irwin RS, CHEST Expert Cough Panel. Tools for assessing outcomes in studies of chronic cough: CHEST guideline and Expert Panel report. Chest. 2015 Mar;147(3):804-14. [111 references] PubMed

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2015 Mar

# Guideline Developer(s)

American College of Chest Physicians - Medical Specialty Society

# Source(s) of Funding

Funding/Support

Funding was provided by the American College of Chest Physicians (CHEST).

#### Guideline Committee

Expert Cough Panel

# Composition of Group That Authored the Guideline

Expert Panel Members: Louis-Philippe Boulet, MD, FCCP; Remy R. Coeytaux, MD, PhD; Douglas C. McCrory, MD, MHS; Cynthia T. French, PhD, RN, FCCP; Anne B. Chang, MBBS, PhD, MPH; Surinder S. Birring, MBChB, MD; Jaclyn Smith, MBChB, PhD; Rebecca L. Diekemper, MPH; Bruce Rubin, MD, MEngr, MBA; Richard S. Irwin, MD, Master FCCP

### Financial Disclosures/Conflicts of Interest

#### Financial/Nonfinancial Disclosures

The authors have reported to *CHEST* the following conflicts of interest: Drs Coeytaux and McCrory are authors on the Agency for Healthcare Research and Quality (AHRQ) evidence report on which this guideline is based, and their efforts on this project were supported by a contract from AHRQ. Dr French is a codeveloper and co-copyright holder of the Cough-Specific Quality-of-Life Questionnaire. She has not received any financial compensation for Cough-Specific Quality-of-Life Questionnaire in >3 years. Dr Chang is a codeveloper of the Parent Cough-Specific Quality of Life Questionnaire, a member of the advisory panel for the AHRQ systematic review on assessing cough severity, and a reviewer of the final AHRQ document. Dr Birring is a developer of the adult quality of life (QoL) and cough counting tools. Dr Smith has a patent for a cough counting device. Dr Irwin is a codeveloper and co-copyright holder of the Cough-Specific Quality-of-Life Questionnaire. He has not received any financial compensation for Cough-Specific Quality-of-Life Questionnaire in >3 years. Dr Irwin was also a member of the advisory panel for the AHRQ systematic review on assessing cough severity and a reviewer of the final AHRQ document. Although Dr Irwin is the Editor in Chief of

CHEST, all reviews and decisions made concerning this manuscript were made by others, independent of Dr Irwin. Drs Boulet and Rubin and Ms Diekemper have reported that no potential conflicts of interest exist with any companies/organizations whose products or services may be discussed in this article.

Also see the methodology document (see the "Availability of Companion Documents" field) for a discussion of the American College of Chest Physicians' disclosure policies.

### Guideline Endorser(s)

American Academy of Otolaryngology - Head and Neck Surgery Foundation - Medical Specialty Society

American Thoracic Society - Medical Specialty Society

Asian Pacific Society of Respirology - Disease Specific Society

Canadian Thoracic Society - Medical Specialty Society

Irish Thoracic Society - Medical Specialty Society

### Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

# Guideline Availability

Available from the CHEST Journal Web site		. Also available to CHEST Journal subscribers through the CHEST	Г арр
	for iPhone and iPad		

# Availability of Companion Documents

The following are available:

### Methodology Documents

,	McCrory DC, Coeytaux RR, Yancy WS Jr, Schmit KM, Kemper AR, Goode A, Hasselblad V, Heidenfelder BL, Irvine RJ, Musty MD,
	Gray R, Sanders GD. Assessment and management of chronic cough. Comparative effectiveness review No. 100. AHRQ Publication No.
	13-EHC032-EF. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2013 Jan. Errata 2014 Mar. 256 p. Available
	from the Agency for Healthcare Research and Quality (AHRQ) Web site
,	Lewis SZ, Diekemper RL, French CT, Gold PM, Irwin RS. Methodologies for the development of the management of cough: CHEST
	guideline and Expert Panel report. Chest. 2014 Nov;146(5):1395-402. Available from the CHEST Journal Web site
	Schmit KM, Coeytaux RR, Goode AP, McCrory DC, Yancy WS Jr, Kemper AR, Hasselblad V, Heidenfelder BL, Sanders GD.
	Evaluating cough assessment tools: a systematic review. Chest. 2013 Dec;144(6):1819-26. Available from the CHEST Journal Web site
	Schmit KM, Coeytaux RR, Goode AP, McCrory DC, Yancy WS Jr, Kemper AR, Hasselblad V, Heidenfelder BL, Sanders GD.
	Evaluating cough assessment tools: a systematic review. Online supplement. Chest. 2013 Dec. 15 p. Available from the CHEST Journal
	Web site
	Lewis SZ, Diekemper RL, Ornelas J, Casey KR. Methodologies for the development of CHEST guidelines and Expert Panel reports.
	Chest. 2014 Jul;146(1):182-192. Available from the CHEST Journal Web site

Methods guide for effectiveness and comparative effectiveness reviews. AHRQ Publication No. 10(14)-EHC063-EF. Rockville (MD):

• Methods guide for medical test reviews. AHRQ Publication No. 12-EHC017. Rockville (MD): Agency for Healthcare Research and

Agency for Healthcare Research and Quality (AHRQ); 2014 Jan. 384 p. Available from the AHRQ Web site

•	Boulet LP, Coeytaux RR, McCrory DC, French CT, Chang AB, Birring SS, Smith J, Diekemper RL, Rubin B, Irwin RS, CHEST Expert
	Cough Panel. Tools for assessing outcomes in studies of chronic cough: CHEST guideline and Expert Panel report. Online supplement.
	Chest. 2015 Mar. 6 p. Available from the CHEST Journal Web site
•	Irwin RS, French CT, Lewis SZ, Diekemper RL, Gold PM. Overview of the management of cough: CHEST guideline and Expert Panel
	report. Chest. 2014 Oct;146(4):885-89. Available from the CHEST Journal Web site
•	Canning BJ, Chang AB, Bolser DC, Smith JA, Mazzone SB, McGarvey L. Anatomy and neurophysiology of cough: CHEST guideline and
	Expert Panel report. Chest. 2014 Dec;146(6):1633-48. Available from the CHEST Journal Web site
•	French CT, Diekemper RL, Irwin RS. Assessment of intervention fidelity and recommendations for researchers conducting studies on the
	diagnosis and treatment of chronic cough in the adult: CHEST guideline and Expert Panel report. Chest. 2015 Jul;148(1):32-54. Available
	from the CHEST Journal Web site.
•	Management of cough: overview of CHEST guideline and Expert Panel report. Podcast. 2014 Oct. Available from the CHEST Journal
	Web site

### Patient Resources

Other Companion Documents

None available

### **NGC Status**

This NGC summary was completed by ECRI Institute on September 22, 2015.

Quality (AHRQ); 2012 Jun. 188 p. Available from the AHRQ Web site

# Copyright Statement

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

# Disclaimer

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